

JUDGE C. V. ...

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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NANCY CLAYTON
and ZANE A. MIRANDA (H/W)

Plaintiffs,

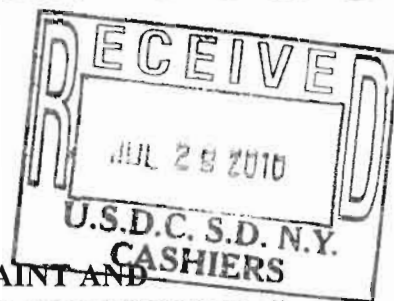
-against-

BRUCE E. KATZ, M.D.
JUVA SKIN & LASER CENTER,
and CYNOSURE, INC.

Defendants.
-----X

Case No.

COMPLAINT AND
DEMAND FOR JURY TRIAL



Plaintiff Nancy Clayton ("Clayton" or "Plaintiff"), by and through her attorneys, Fox Rothschild LLP, as and for her Complaint against Defendants Bruce E. Katz, M.D., ("Katz"), JUVA Skin & Laser Center ("JUVA") and Cynosure, Inc. ("Cynosure"), alleges as follows:

THE PARTIES

1. Plaintiff is an adult individual and is a citizen of the State of California residing at 202 Villa Point, Newport Beach, CA 82660.

2. Plaintiff Zane A. Miranda ("Miranda") is an adult individual and is a citizen of the State of California residing at 202 Villa Point, Newport Beach, CA 82660.

3. Defendant Katz is an adult individual and is a physician licensed to practice medicine in the State of New York. Defendant's principal place of business is located at 60 East 56th Street, New York, NY 10022.

4. Defendant JUVA is a corporation or other business entity organized and existing under the laws of the State of New York with its principal place of business located at 60 East 56th Street, New York, NY 10022.

5. Defendant Cynosure is a corporation or other business entity organized and existing under the laws of the State of Delaware with its principal place of business located at 5 Carlisle Road, Westford, MA 01886.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action based on diversity of citizenship pursuant to 28 U.S.C. §1332.

7. Defendants are subject to jurisdiction here, because, for among other reasons, they do business in the State of New York and Defendants transact and solicit business in the State of New York.

8. Venue is proper in this District under 28 U.S.C. § 1391(b).

9. Venue is also proper here because substantial parts of the acts giving rise to the claims here occurred in the federal judicial district for the Southern District of New York as aforesaid.

ALLEGATIONS COMMON TO ALL CAUSES OF ACTIONS

10. On or about February 7, 2008, Plaintiff was evaluated by Defendant Katz for a potential smart liposuction procedure to the cheeks to improve Plaintiff's appearance.

11. At the time of her initial evaluation, Plaintiff informed Defendant Katz that she had undergone prior cosmetic surgery including, without limitation, silicone injections to her cheeks.

12. Plaintiff believes and therefore avers that she was a poor candidate for smart liposuction procedure due to, inter alia, the absence of any significant fatty tissue or about the Plaintiff's face.

13. Plaintiff believes and therefore avers that smart liposuction was contraindicated to her face because, inter alia, Plaintiff had previously undergone silicone injections to her face.

14. Notwithstanding the foregoing, Defendant Katz recommended that Plaintiff undergo the smart liposuction procedure.

15. The procedure was carried out on May 7, 2008 and was performed by Defendant Katz at the JUVA Skin & Laser Center in New York City.

16. The procedure was carried out with a device known as an Smartlipo MPX laser (the “Smartlipo Laser”) which was manufactured and marketed by Cynosure, Inc. (“Cynosure”).

17. As a result of the procedure, Plaintiff sustained extremely serious burns to her face which have resulted in permanent injuries described more fully herein.

AS AND FOR A FIRST CAUSE OF ACTION
(Medical Malpractice)
Plaintiff v. Katz

18. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

19. At all times relevant hereto, Defendant Katz owed a duty to Plaintiff to discharge his professional obligations as a physician within an acceptable standard of medical care within the medical community.

20. At all times relevant hereto, Defendant Katz’s care and treatment of the Plaintiff fell below the applicable standard of care and caused harm to the Plaintiff as complained of herein.

21. The negligence, carelessness and medical malpractice of Defendant Katz consisted, inter alia, of the following:

- a. Failing to properly treat Plaintiff during the period of time treatment was provided and especially failing to properly perform a smartlipo procedure;
- b. Utilizing a procedure that was inappropriate and/or contraindicated under the circumstances;
- c. Utilizing a medical device that was inappropriate, unsafe and/or contraindicated under the circumstances;

d. Failing to perform the aforementioned procedure in a technically competent manner resulting in the burning of the plaintiff's face;

e. Delivering excessive energy to a small point on Plaintiff's face through a unreasonably large cannula;

f. Failing to properly and adequately consider more appropriate treatment alternatives before recommending the aforementioned procedure;

g. Failing to properly monitor the procedure to ensure that it was carried out without causing serious and permanent burns to the plaintiff's face;

h. Failing to utilize, contact, make available and consult competent and experienced physicians, consultants and personnel in examining and treating the Plaintiff;

i. Failing to have adequate experience and/or competence in administering and/or carrying out the aforementioned procedure;

j. Holding himself out as competent and skillful to provide adequate medical care and inducing and enticing Plaintiff into relying upon same and then failing to provide same;

k. Failing to adequately follow up on Plaintiff's care;

l. Failing to possess the degree of knowledge and skill ordinarily possessed by other physicians;

m. Being otherwise negligent, careless and reckless as may be demonstrated at trial or determined through discovery.

22. As a direct and proximate result of Defendant Katz's negligence, carelessness and medical malpractice Plaintiff: 1) suffered conscious pain and suffering in the past and will suffer conscious pain and suffering into the future, 2) incurred medical expenses in the past and will incur future medical expenses, 3) suffered mental anguish, 4) suffered permanent physical injuries and

disfigurement, and 5) was and will be required to undergo additional medical procedures and has sustained other damages.

23. The injuries and damages sustained by Plaintiff were the direct and proximate result of the negligent actions of Defendant Katz, and occurred without any act or omission on the part of the Plaintiff directly thereunto contributing.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendant Katz together with costs and such other relief as may be just and equitable under the circumstances.

AS AND FOR A SECOND CAUSE OF ACTION

(Vicarious Liability)

Plaintiff v. JUVA

24. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

25. Defendant JUVA is vicariously liable to Plaintiff from the negligent acts and/or omissions of Defendant Katz, all of which were performed in the course and scope of his employment and/or agency (actual and/or ostensible) with Defendant JUVA.

26. As a direct and proximate result of Defendant JUVA's negligence, carelessness and medical malpractice, Plaintiff: 1) suffered conscious pain and suffering in the past and will suffer conscious pain and suffering into the future, 2) incurred medical expenses in the past and will incur future medical expenses, 3) suffered mental anguish, 4) suffered permanent physical injuries and disfigurement, and 5) was and will be required to undergo additional medical procedures and has sustained other damages.

27. The injuries and damages sustained by the Plaintiff were the direct and proximate result of the negligent actions of Defendant JUVA and occurred without any act or omission on the part of the Plaintiff directly thereunto contributing.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendant JUVA together with costs and such other relief as may be just and equitable under the circumstances.

AS AND FOR A THIRD CAUSE OF ACTION

(Breach of Warranty)

Plaintiff v. Katz and Juva

28. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

29. At all times relevant hereto, Defendant Katz, on behalf of himself and Defendant JUVA, made statements, representations, promises and/or description regarding his ability to improve Plaintiff's physical appearance and/or achieve certain results.

30. Defendants' actions and the results achieved failed to conform to the statements, representations, promises and/or descriptions made by Defendant Katz to Plaintiff and Defendants breached express and implied warranties associated with the care and treatment rendered.

31. As a direct and proximate result of Defendants Katz and JUVA's negligence, carelessness and medical malpractice, Plaintiff: 1) suffered conscious pain and suffering in the past and will suffer conscious pain and suffering into the future, 2) incurred medical expenses in the past and will incur future medical expenses, 3) suffered mental anguish, 4) suffered permanent physical injuries and disfigurement, and 5) was and will be required to undergo additional medical procedures and has sustained other damages.

32. The injuries and damages sustained by the Plaintiff were the direct and proximate result of the negligent actions of Defendants Katz and JUVA and occurred without any act or omission on the part of the Plaintiff directly thereunto contributing.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendant Katz and Defendant JUVA together with costs and such other relief as may be just and equitable under the

circumstances.

AS AND FOR A FOURTH CAUSE OF ACTION
(Lack of Informed Consent)
Plaintiff v. Katz and JUVA

33. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

34. At all times relevant hereto, Defendants Katz and JUVA failed to disclose all material facts before obtaining Plaintiff's consent to the procedure.

35. In particular, Defendants Katz and JUVA failed to disclose inter alia, that the SmartLipo Laser utilized on Plaintiff was experimental, that it had not been used for any significant period of time, that other Cynosure-trained physicians had declared the device to be unsafe, and that Defendant Katz was affiliated in and/or had an interest in Cynosure, the device manufacturer.

36. The undisclosed information would have factored substantially in Plaintiff's decision whether to undergo the procedure.

37. Had Defendants Katz and JUVA revealed and disclosed all material facts including, without limitation, the facts set forth in Paragraph 35 of this Complaint, Plaintiff would not have consented to and/or undergone the procedure.

38. As a direct and proximate result of the foregoing acts of negligence, carelessness and medical malpractice Plaintiff: 1) suffered conscious pain and suffering in the past and will suffer conscious pain and suffering into the future, 2) incurred medical expenses in the past and will incur future medical expenses, 3) suffered mental anguish, 4) suffered permanent physical injuries and disfigurement, and 5) was and will be required to undergo additional medical procedures and has sustained other damages.

39. The injuries and damages sustained by the Plaintiff were the direct and proximate result of the negligent actions of Defendants and occurred without any act or omission on the part of the Plaintiff directly thereunto contributing.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendant Katz and Defendant JUVA together with costs and such other relief as may be just and equitable under the circumstances.

AS AND FOR A FIFTH CAUSE OF ACTION
(Unfair/Deceptive Trade Practices – NYGBL § 349)
Plaintiff v. Katz, JUVA and Cynosure

40. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

41. Defendants actively marketed the procedure known as laser assisted lipolysis through the use of a Cynosure SmartLipo Laser as being safe, efficacious and superior to other comparable cosmetic procedures.

42. Plaintiff believes and therefore avers that in fact, the procedure was of an experimental nature and had not been determined to be safe, efficacious and superior to other comparable cosmetic procedures.

43. Furthermore, Plaintiff believes and therefore avers that she was treated with a laser device which had not been approved by the FDA or, alternatively, that she was treated with an approved device except that Defendants failed to disclose material facts to the FDA regarding the safety and efficacy of the procedure and the device.

44. Furthermore, Plaintiff believes and therefore avers that she was treated with a laser device which was designed and manufactured to deliver significant energy output over a condensed

period of time which allowed a physician to treat a greater number of patients in any given day. Plaintiff further believes that the increased energy output endangered her health and safety.

45. Furthermore, Plaintiff believes and therefore avers that Defendants Katz and Juva have an ongoing affiliation and/or relationship with the device manufacturer, Cynosure, and that they failed to disclose to Plaintiff said affiliation as well as the existence of direct and/or indirect remuneration, compensation and/or incentives as between Defendants Katz and JUVA and Defendant Cynosure.

46. As a direct and proximate result of the foregoing acts of negligence, carelessness and medical malpractice Plaintiff: 1) suffered conscious pain and suffering in the past and will suffer conscious pain and suffering into the future, 2) incurred medical expenses in the past and will incur future medical expenses, 3) suffered mental anguish, 4) suffered permanent physical injuries and disfigurement, and 5) was and will be required to undergo additional medical procedures and has sustained other damages.

47. The injuries and damages sustained by the Plaintiff were the direct and proximate result of the negligent actions of the Defendants occurred without any act or omission on the part of the Plaintiff directly thereunto contributing.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants, jointly and severally, together with costs and such other relief as may be just and equitable under the circumstances.

AS AND FOR A SIXTH CAUSE OF ACTION

(Breach of Contract)

Plaintiff v. Katz and JUVA

48. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

49. Plaintiff contracted and paid for medical services with the expectation that they would be performed in a non-negligent manner and achieve the promised results.

50. By reason of the aforesaid, Defendants Katz and JUVA breached their contract with Plaintiff.

51. By reason of the aforesaid, Plaintiff sustained damages as heretofore alleged.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants Katz and Defendant JUVA together with costs, pre-judgment interest, and such other relief as may be just and equitable under the circumstances.

AS AND FOR A SEVENTH CAUSE OF ACTION
(Products Liability)
Plaintiff v. Cynosure

52. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

53. At all times relevant hereto, Defendant Cynosure was in the business of selling the SmartLipo Laser.

54. At all times relevant hereto, Defendant Cynosure manufactured and/or introduced into the stream of commerce a defective product in an unreasonably dangerous condition which was expected to and did reach a user or consumer without substantial change in the condition in which it was sold.

55. In particular, the SmartLipo Laser was designed and/or manufactured in a manner that allowed excessive energy to be delivered to the plaintiff's face without the ability to accurately monitor the temperature of the skin and underlying tissue thereby creating an unreasonable risk of harm.

56. The SmartLipo laser, as manufactured, deviated from the acceptable design and/or quality standards.

57. The SmartLipo laser, as designed, was not reasonably safe and the defective design was a substantial factor in causing the plaintiff's injury.

58. Defendant Cynosure knew or should have known that the SmartLipo laser created an unreasonable risk of harm when used as intended and failed to warn Plaintiff and/or others regarding said harm both before and after the device was introduced into the stream of commerce.

59. As a direct and proximate result of the foregoing Plaintiff: 1) suffered conscious pain and suffering in the past and will suffer conscious pain and suffering into the future, 2) incurred medical expenses in the past and will incur future medical expenses, 3) suffered mental anguish, 4) suffered permanent physical injuries and disfigurement, and 5) was and will be required to undergo additional medical procedures and has sustained other damages.

60. The injuries and damages sustained by the Plaintiff were proximately caused by the dangerous and defective device manufactured and introduced into the stream of commerce by Defendant Cynosure and occurred without any act or omission on the part of the Plaintiff directly thereunto contributing.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendant Cynosure together with costs and such other relief as may be just and equitable under the circumstances.

AS AND FOR A EIGHTH CAUSE OF ACTION
(Negligence)
Plaintiff v. Cynosure

61. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

62. At all times relevant hereto, Defendant Cynosure expected and anticipated that the SmartLipo laser would be used on patients including, without limitation, the plaintiff.

63. At all times relevant hereto, Defendant Cynosure expected and anticipated that the SmartLipo laser would be used for purposes of laser assisted lipolysis.

64. At all times relevant hereto, Defendant Cynosure expected and anticipated that the SmartLipo laser would be applied to the plaintiff's face.

65. At all times relevant hereto, Defendant Cynosure was under an obligation to manufacture and distribute medical devices that were safe and efficacious.

66. Plaintiff believes and therefore avers that Defendant Cynosure designed, manufactured and tested the device in a negligent manner.

67. Plaintiff believes and therefore avers that Defendant Cynosure was negligent in failing to adequately warn patients and/or physicians utilizing the SmartLipo device in regard to the possibility of severe burns particularly where the patient has had prior fillers injected to the face.

68. As a direct and proximate result of the foregoing Plaintiff: 1) suffered conscious pain and suffering in the past and will suffer conscious pain and suffering into the future, 2) incurred medical expenses in the past and will incur future medical expenses, 3) suffered mental anguish, 4) suffered permanent physical injuries and disfigurement, and 5) was and will be required to undergo additional medical procedures and has sustained other damages.

69. The injuries and damages sustained by the Plaintiff were proximately caused by the dangerous and defective device manufactured and introduced into the stream of commerce by Defendant Cynosure and occurred without any act or omission on the part of the Plaintiff directly thereunto contributing.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendant Cynosure together with costs and such other relief as may be just and equitable under the circumstances.

AS AND FOR A NINTH CAUSE OF ACTION
(Breach of Warranty)
Plaintiff v. Cynosure

70. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

71. At all times relevant hereto, Defendant Cynosure sold the SmartLipo Laser with knowledge, actual and/or constructive, that it would be used on a patient's face.

72. At all times relevant hereto, Defendant Cynosure made express and implied warranties that the SmartLipo Laser was safe for the ordinary purpose for which it was sold.

73. At all times relevant hereto, a defect existed when the product was under Defendant Cynosure's control.

74. At all times relevant hereto, the plaintiff was injured as a result of the defect.

75. As a direct and proximate result of the foregoing Plaintiff: 1) suffered conscious pain and suffering in the past and will suffer conscious pain and suffering into the future, 2) incurred medical expenses in the past and will incur future medical expenses, 3) suffered mental anguish, 4) suffered permanent physical injuries and disfigurement, and 5) was and will be required to undergo additional medical procedures and has sustained other damages.

76. The injuries and damages sustained by the Plaintiff were proximately caused by the dangerous and defective device manufactured and introduced into the stream of commerce by Defendant Cynosure and occurred without any act or omission on the part of the Plaintiff directly thereunto contributing.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendant Cynosure for breach of implied and express warranties together with costs and such other relief as may be just and equitable under the circumstances.

AS AND FOR A TENTH CAUSE OF ACTION
(Agency/Joint Venture)
Plaintiff v. Cynosure

77. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

78. At all times relevant hereto, Defendants Katz and JUVA functioned as the actual and/or ostensible agent of Defendant Cynosure.

79. In particular, Defendants Katz and JUVA, inter alia: (a) promoted, marketed Cynosure technology including, without limitation, the SmartLipo Laser; (b) held JUVA out as a Cynosure-approved facility and/or center of excellence; (c) actively advocated for the use of Cynosure technology; (d) trained other physicians in laser lipolysis utilizing only Cynosure technology; (e) authored articles and publications on behalf of Cynosure; (f) received, upon information and belief, a revenue share in regard to his Cynosure-related activities; and (g) engaged in such other acts which create actual and/or ostensible agency and/or the existence of a joint venture as may be revealed in the course of discovery.

80. The aforesaid was undertaken with the knowledge and consent of Defendant Cynosure.

81. By reason of the aforesaid, Defendant Cynosure is liable for the acts and/or omissions of Defendants Katz and JUVA performed in the course and scope of their agency.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendant Cynosure together with costs and such other relief as may be just and equitable under the circumstances.

AS AND FOR A ELEVENTH CAUSE OF ACTION
(Punitive Damages)
Plaintiff v. All Defendants

82. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

83. Defendants marketed and used the SmartLipo Laser without obtaining premarket notification clearance from the Food and Drug Administration (the “FDA”) as required by Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the “Act”).

84. Alternatively, to the extent that Defendants sought and obtained premarket clearance from the FDA for the marketing of the SmartLipo Laser, Defendants failed to inform patients including, without limitation, the Plaintiff herein, that the technology was experimental and that additional studies and testing was necessary to determine the efficacious use of the device.

85. Alternatively, to the extent that Defendants obtained permission from the FDA to market the device based on representations that the SmartLipo Laser was substantially equivalent to a predicate device, such representation was incorrect as it pertained to the use of the SmartLipo Laser for laser lipolysis of, inter alia, the face, a such intended use was not indicated in any predicate device.

86. In addition to the foregoing, Defendants were required to disclose device-related adverse events pursuant to the Act.

87. Defendants failed to disclose any adverse events to the FDA stemming from the Plaintiff’s treatment.

88. Plaintiff believes and therefore avers that Defendants failed to disclose adverse events with regard to other patients.

89. Had the adverse events been properly reported, Plaintiff would have been able to obtain better information regarding the efficacy of the procedure and regulators would have been able to better monitor the use of the device and protect the public health.

90. Furthermore, Plaintiff believes and therefore avers that at least one Cynosure trained physician disseminated an “open letter” to Cynosure and to Defendant Katz warning Defendants that the SmartLipo Laser, as manufactured and/or marketed, posed serious safety risks.

91. Defendants' actions constitute a willful, wanton and/or reckless disregard for Plaintiff's safety all of which are outrageous and justify the imposition of punitive damages.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants Katz, JUVA and Cynosure together with costs and such other relief as may be just and equitable under the circumstances.

AS AND FOR A TWELFTH CAUSE OF ACTION

(Loss of Consortium)

Plaintiff Miranda v. All Defendants

92. Plaintiff repeats and re-alleges each and every allegation set forth above with the same force and effect as if fully stated herein.

93. At all times relevant hereto, Plaintiff Miranda was lawfully married to Plaintiff, Nancy Clayton.

94. By reason of the aforesaid, Plaintiff Miranda has been deprived of the companionship, society and affection of Plaintiff, Nancy Clayton.

95. **WHEREFORE**, Plaintiff demands judgment in her favor and against Defendants Katz, JUVA and Cynosure together with costs and such other relief as may be just and equitable under the circumstances.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury as to all issues properly so tried.

Dated: New York, New York

July ~~27~~ 2010

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